REMARKS

Claims 1-3, 5-8, 10-13, 29-32, 45-48, and 50-84 are pending in the application. Claims 73-84 are newly added. No new matter has been added.

Claims 1-3, 5, 45, 47, 48, 50, 71, and 72 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Dang et al. (U.S. Patent No. 6,758,859) ("Dang").

Applicant would like to thank Examiner Nguyen as well as Examiner Hayes for the telephonic interviews. Although the Applicant had a difficult time understanding the underlying basis for Examiner Nguyen's position, Applicant very much appreciates the time and effort provided. The underlying basis for the rejection became more apparent during the interview with Examiner Hayes. Examiner Hayes indicated that in his opinion the claims could be read broadly so as to be anticipated by a stent made from gold. More particularly, Examiner Hayes indicated that in his opinion a gold stent is equivalent to stent "carrying gold." Examiner Hayes acknowledged that if a better distinction could be drawn between the second material and the material from which the stent is made, then the teaching of Dang could be overcome. Applicant suggested the language of the second material being disposed over a surface of the depots. Examiner Hayes, although not committing to this language, acknowledged that this provides for a good distinction that would probably overcome Dang. Examiner Hayes also suggested the second material being different than the material of the stent body as a basis to overcome the rejection.

In sum, in light of the discussions with Examiner Hayes, claim 1 has been amended to "wherein the second material **is in the depots of the stent** body **and wherein the second material is disposed over a surface of the depots**." Additionally, claim 45 has been amended to "wherein the **second material is deposited in the cavities** of the stent body **and over the**

surface of the cavities." New claim 73 has been provided to capture the language suggestion by Examiner Hayes -- namely, "wherein the second **material is in the depots of the stent body** and **the second material is different than surface material of the depots**.

In addition to the above summation of the interview, Applicant further responds to the office action as follows:

On page 2 of the office action, the first paragraph, the Examiner has stated that Dang shows in figures 3 and 4 a stent with depots. The Applicant does not disagree with the Examiner on this point. The Examiner is correct.

On page 2 of the office action, the Examiner has claimed that Dang teaches a first material that includes a therapeutic substance on col. 5, lines 5-22. The Applicant does not disagree with the Examiner on this point. The Examiner is correct that depots of the Dang stent carry a therapeutic substance.

On page 2 of the office action, the Examiner has stated that Dang teaches

> **a second material (col. 4, lines 17-40) configured to convert a first type of energy to a second type of energy. Note that cols. 5, lines 10-14 and lines 54-66 can be interpreted broadly that radioactive isotopes for stent usage can be converted from its energy conversion material which is disposed in depots (30) of the stent**.

The Applicants respectfully submit that the Examiner is unequivocally incorrect with regard to every single element and aspect of this sentence.

First, the Examiner refers to col. 4, lines 17-20 which recites material that the stent body is made from. Then the Examiner states that col. 5, lines 54-66 can be interpreted broadly with respect to the radioactive isotopes so that the isotopes are equivalent to the second material as claimed. Applicant is immensely puzzled by what col. 4 has to do with col. 5. Col. 4 teaches that a stent can be made from metals and alloys. Col. 5 teaches that radioactive isotopes can be

used in the stent's depots made from the metals and alloys of col. 4. Applicant respectfully submits that the Examiner has completely commingled these two columns (in the statement produced above) and their combination is completely indecipherable as well as incomprehensible. Col 4. has nothing to do with Col. 5. Again, one teaches stent body material and the other teaches radiation therapy.

Second, if the Examiner is equating the claimed element of a **second material** configured to convert a first type of energy received by the second material to a second type of energy to the teaching of col. 4, lines 17-40, then Dang now unequivocally fails to teach what is claimed. Claims 1 and 45 have been amended to recite, "wherein the **second material is in the depots** of the stent body and wherein the **second material is disposed over a surface of the depots,**" and "wherein the **second material is deposited in the cavities** of the stent body **and over the surface of the cavities,**" respectively. These amendments were discussed with Examiner Hayes and based on the discussion with Examiner Hayes Applicant believes that the provided language should be sufficient to overcome the rejection.

Third, if the Examiner is equating the claimed element of a second material in the depots to the radioactive isotope of col. 5, line 54-66, then Applicant respectfully submits that Dang would again fail as a reference. Dang teaches that either a drug **OR** a radioactive isotope can be used. Dang clearly presents the radioactive isotope as an **alternative** form of treatment to a drug. For example, on col. 5 Dang teaches that "yet in other embodiments" a radioactive isotope can be used. Moreover, as indicated in the previous response, the second and third paragraphs of col. 6 teach that the **depots have to be of a first size to accommodate the drug and a second size to accommodate the radioactive isotopes**. Moreover, it is clearly apparent to one having

ordinary skill in the art that combining a radioactive isotope with a drug may lead to degradation of the drug. Therefore it would be counterintuitive to combine the two.

Nowhere in Dang is the **concomitant combination of a drug and a radioactive material disclosed**. Again, Dang fails to teach using a drug in combination with the radioactive isotope. **If the examiner is equating the first material of the claims with the drug and the second material of the claims with the radioactive isotope to cause the release of the drug, then the Examiner's combination is baseless since Dang fails to teach the use of the first material/drug in combination with the second material/radioactive isotope**. Accordingly, claims 1-3, 5, 45, 47, 48, 50, 71 and 72 are patentable over Dang. Removal of the rejection is respectfully requested.

Applicants also respectfully submit that the Examiner has failed to address the Applicant's position in the previous response. Particularly, Applicant submitted that if, for the sake of argument, Dang does in fact teach the combination of using a drug and a radioactive agent for the release of the drug, this teaching would still fall short of what has been claimed. Dang still does **not teach that the second type of energy from the second material would promote release of the therapeutic substance** as claimed. The size of the radioactive material, the shape of the material, or the number or amount of the material could be well short of being capable of promoting the release a therapeutic substance. Moreover, the positioning of the Dang radioactive material could be such as to not be able to promote the release of the therapeutic substance. **Dang is simply not enabling with respect to these issues**. The Examiner is making a tenuous leap and many conjectures about the teachings of Dang that fall well short of what has been claimed. Again, in the current office action, the Examiner is simply brushing over all this issues and the office action is well short of what is mandated by the USPTO.

The Examiner has indicated that Figures 4 and 5a of Dang teaches a topcoat. **Nowhere in Dang is a topcoat described**. As indicated by the Brief Description of the Drawings, Figure 4 illustrates a portion of an implantable device having depots on the surface of the device. The depots are clearly shown by circles 30. Figure 5a is a cross-section of a strut showing the depots. Applicant respectfully fails to see how the Examiner could reasonably contend that Figures 4 and 5a show a topcoat. **There are absolutely no markings of any sort to indicate that Figure 4 or 5a of Dang includes a topcoat**. **If a topcoat was included in the figure, one would assume the specification would have some kind of description, no matter how brief and the figure would have some kind of depiction or reference number, no matter how non-illustrative**.

On page 5 of the office action, the Examiner has indicated that col. 8, lines 48-65 teach a topcoat. **Applicant fails to see any reference to a topcoat in col. 8, lines 48-65. The passage referred to by the Examiner is about increasing the amount of stent material around the depots for reinforcement of the stent strut**. Applicants, with all due respect, are dumfounded by the Examiner's explanation and support in Dang for a topcoat layer.

Claims 6, 11-13, 31, 32, 51, 56-61 and 67 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dang. Applicant presents the following:

A. The Examiner is contending that even though Dang is silent regarding the use of Au particles having silica nano-particle core or a temperature sensitive hydrogel material, it would have been obvious to one having ordinary skill in the art, at the time of the invention, to use such particles and materials. In support of this position, the Examiner has cited In re Leshin, 125 USPQ 416. Applicant respectfully disagrees with the Examiner's position.

First, **Dang simply fails to teach the use of any kind of particles**. **If Dang fails to teach particles, then it is certainly not obvious to one having skill in the art to select gold as the particle of choice. Dang uses gold to form the body of the stent. Again, nowhere in Dang is the use of particles disclosed**.

Second, the mode of drug release of Dang -- namely, simple release action of a drug out from stent depots, is vastly different than the "pump" release action of the present invention. The Applicant respectfully submits that the Examiner's contention, that it would be obvious to use the material of Dang with the mechanism of the present invention, is technically without merit since the modes of drug delivery are action are vastly different.

Third, Applicant respectfully submits that the facts of In re Leshin are vastly different from what has been presented in the application at bar. In re Leshin is not remotely applicable to this invention. Claim 13 of Leshin, which was in dispute, did **not recite any kind of material**. The court held that **because "the material of which the device is made is not specified [by claim 13], patentability of the claim cannot be predicted on the use of plastics**."

Dang teaches gold to make the body of the stent. It does not teach gold in particle form as a means to deliver a drug. The Examiner is taking a material for one purpose (stent structure) and is suggesting that its use for a completely and vastly different purpose (pump action drug delivery) is obvious. The Examiner is taking the material in one form (stent body form) and is saying that a completely different form of this material (particle form) is obvious. **Unlike In re Leshin where a similar material was disclosed for similar purpose, Dang does not teach any similar material used for a similar purpose**.

Moreover, **Applicant has failed to find any reference to a hydrogel material in the Dang reference as contended by the Examiner**.

Fourth, since the Examiner has failed to provide any reference in support of the missing elements, and has merely concluded that it would be an obvious choice of using the particles as claimed, Applicant is assuming that the Examiner is relying on common knowledge in the art, under MPEP 2144.03. If the applicant challenges the Examiner's assertion, the Examiner **MUST** support the finding with adequate evidence. **Based on the reasons provided above, Applicants traverse the Examiner's assertion and request that the Examiner provide proof in the form of an affidavit or secondary evidence.**

B. With respect to claims 29, 30, 52 and 53, the Examiner's position is that even though Dang is silent regarding the diameter of the Au particles, since Dang discloses Au particles, change in size would be routine to one skilled in the art.

First, as indicated above, Dang does NOT teach Au particles. **In fact, Dang does NOT teach any kind of particles**. Again, this was presented in the previous response only to be ignored by the Examiner. Dang teaches that the stent struts or stent body can be laser cut from gold. Gold aside, even with respect to the radioactive isotopes, **Dang fails to teach that these isotopes can be in particle form**.

Second, as indicated in the specification, size and thickness have an integral role in peak absorbance and thermal output energy, among other factors. Accordingly, size and thickness adjustment play an important factor that goes beyond simple, routine experimentation. The Examiner should not trivialize this size selection as routine experimentation.

Third, regardless of the above points, claims 29, 30, 52, and 53 depend on claims 1 and 45 and are patentably allowable for at least the same reasons.

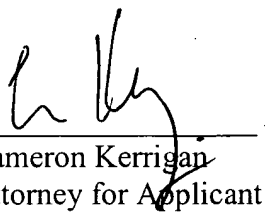
Claims 7, 8, 54, 55, 62, 63, 64, 68, 69, and 70 have been allowed.

CONCLUSION

Removal of all rejections is respectfully requested. Applicant respectfully requests the Examiner to enter the foregoing amendments and pass the case to issue.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

Respectfully submitted,



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